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MCDONNELL BOEHNEN HULBERT & BERGHOFF LLP
300 S. WACKER DRIVE
32ND FLOOR
CHICAGO, IL 60606

EXAMINER	
GODDARD, LAURA B	
ART UNIT	**PAPER NUMBER**
1642	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/520,142	RONINSON ET AL.	
	Examiner	Art Unit	
	Laura B. Goddard, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,2,4,7-10,13,14,16,19-23,26,27,29-31,34,35,37-39,42,43,45,48,49,51,52,55,56,58,61-65,68,69,71-73,76,77,79-81,86-92,97-99,102,104 and 108-111* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1,2,4,7-10,13,14,16,19-23,26,27,29-31,34,35,37-39,42,43,45,48,49,51,52,55,56,58,61-65,68,69,71-73,76,77,79-81,86-92,97-99,102,104 and 108-111.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

NOTE: Claim 50 is withdrawn because it is dependent on a canceled claim.

Group 1, claim(s) 1, 2, 4, 7, 8, 9, 10, 13, 14, 16, 19, 20-23, 26, 27, 29-31, 34, 35, 37-39, drawn to the special technical feature of a method for identifying a compound that induces senescence in a mammalian cell comprising culturing a mammalian cell, in the presence and absence of the compound; assaying the expression of at least one cellular gene in **Table 2A** in said cell in the presence of the compound with the expression of said gene in the cell in the absence of the compound; and identifying compounds that induce senescence when expression of at least one cellular gene in Table 2A is higher in the presence of the compound than in the absence of the compound.

Additionally, Applicants must elect a single or specific combination of genes from Table 2A. Each gene is structurally and functionally distinct and lacks the same or corresponding special technical features.

Group 2, claim(s) 42, 43, 45, 48, 49, 51, 52, 55, 56, 58, 61-65, 68, 69, 71-73, 76, 77, 79-81 drawn to the special technical feature of a method for identifying a compound that induces senescence in a mammalian cell comprising culturing a mammalian cell in the presence and absence of the compound; assaying the expression of at least one cellular gene in **Table 1** in said cell in the presence of the compound with the expression of said gene in the cell in the absence of the compound; and identifying compounds that induce senescence when expression of at least one cellular gene in Table 1 is lower in the presence of the compound than in the absence of the compound.

Additionally, Applicants must elect a single or specific combination of genes from Table 1. Each gene is structurally and functionally distinct and lacks the same or corresponding special technical features.

Group 3, claim(s) 86-92, drawn to the special technical feature of a method for assessing the efficacy of a treatment of a disease or condition relating to abnormal cell proliferation or neoplastic cell growth, the method comprising: obtaining a biological sample comprising cells from an animal having a disease or condition relating to abnormal cell proliferation or neoplastic cell growth before treatment and after treatment; comparing expression of at least one gene in Table 1, 2A, or 2B after treatment with expression of said gene(s) before treatment; and determining that said treatment has efficacy for treating the disease or condition relating to abnormal cell proliferation or neoplastic cell growth if expression of at least one gene in Table 2A and

2B is higher after treatment than before treatment or expression of at least one gene in Table 1 is lower after treatment than before treatment.

Additionally, Applicants must elect a single or specific combination of genes from Table 1, 2A, or 2B. Each gene is structurally and functionally distinct and lacks the same or corresponding special technical features.

Group 4, claim(s) 97-99, 102, 104, drawn to the special technical feature of a method for identifying a compound that inhibits senescence-associated induction of cellular gene expression comprising: (a) contacting the cell with a cytotoxic agent at a concentration of said agent that inhibits cell growth; (b) assaying the cell in the presence and absence of the compound for changes in expression of cellular genes induced when cells become senescent; (c) and identifying the compound as an inhibitor of senescence-associated induction of cellular gene expression if expression of the cellular genes of (b) is induced in the absence of the compound but is not induced in the presence of the compound.

Group 5, claim(s) 108-111, drawn to the special technical feature of a method for determining treatment efficacy in an animal treated with a compound that induces cellular senescence, comprising: assaying a biological fluid from the animal before and after treatment for a senescence marker; and determining that the treatment is effective

when the amount of the marker detected after treatment is greater than the amount of the marker detected before treatment.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups I-V encompass different special technical features identified in the groupings above. The inventions listed above do not relate to a single general inventive concept under PCT Rule 13.1 because under unity of invention between different categories of inventions, unity of invention will only be found to exist if specific combinations of inventions are present.

The allowed combinations do not include multiple methods of using products, as claimed in the instant application. The methods do not share the same method steps, objectives, response variables, and/or criteria for success. Since multiple methods with different special technical features are claimed, Groups I-V are not so linked as to form a single general inventive concept and restriction is proper.

SPECIES ELECTION

Species Election for Group I

A. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of mammalian cell are as follows:

(1) recombinant mammalian cell comprising a reporter gene operably linked to a promoter from a cellular gene in Table 2A) (claims 8, 20, 22, 26, 34, 38 and claims dependent on these); or

(2) a non-recombinant mammalian cell.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each cell is structurally and functionally distinct requiring different agents, mechanisms of action, method steps, and criteria for success to accomplish the assay.

B. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of mammalian cell are as follows (claims 2, 14, 27, 35):

(1) p53 deficient cell;

(2) tumor cell; or

(3) p53 deficient tumor cell.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each cell is structurally, physiologically, and functionally distinct.

C. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of expression detection are as follows (claims 4, 10, 16, 23, 31, 39):

(1) hybridization to a complementary nucleic acid;

(2) using an immunological reagent; or

(3) assaying for an activity of the cellular gene product.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each assay step requires distinct methods steps, reagents, response variables and criteria for success.

D. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of methods are as follows:

(1) further comprising the step of: assaying expression of one or more genes in Table 2B; and identifying compounds wherein expression of the genes in Table 2B is not greater in the presence of the compound than in the absences of the compound (claim 9 or 30);

(2) further comprising assaying the mammalian cell for cell growth and morphological features of senescence; and identifying compounds that induce

senescence when expression of at least one cellular gene in Table 2A is higher in the presence of the compound than in the absence of the compound and the cells are growth-inhibited and express morphological features of senescence in the presence of the compound (claim 13 or 34);

(3) further comprising assaying the mammalian cell for cell growth and morphological features of senescence; and identifying compounds that induce senescence when expression of at least one cellular gene in Table 2A is higher in the presence of the compound than in the absence of the compound and the cells are growth-inhibited and express morphological features of senescence in the presence of the compound (claim 13 or 34) and a method of claim 13 or 20 or 34 further comprising the steps of: assaying expression of one or more genes in Table 2B; and identifying compounds wherein expression of the genes in Table 2B is not greater in the presence of the compound than in the absence of the compound (claim 21 or 22 or 38); or

(4) not further comprising assaying additional genes in Table 2B or assaying for cell growth and morphological features of senescence.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each method is distinct requiring different method steps, objectives, response variables, and/or criteria for success.

If Applicant elects species "(1)" or "(3)" in D above, Applicants must elect a species in E below:

E. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of cellular gene are as follows:

Pick one or a specific combination of gene(s) from Table 2B.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each gene is structurally and functionally distinct.

Species Election for Group II

NOTE: There is no antecedent basis of a "recombinant" mammalian cell as recited in claims 55 and 76.

F. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of mammalian cell are as follows:

(1) recombinant mammalian cell comprising a reporter gene operably linked to a promoter from a cellular gene in Table 2A) (claims 49, 55, 62, 63, 62, 68, 72, 76, 80 and claims dependent on these); or

(2) a non-recombinant mammalian cell.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each cell is structurally and functionally distinct requiring different agents, mechanisms of action, method steps, and criteria for success to accomplish the assay.

G. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of mammalian cell are as follows (claims 43, 56, 69, 77):

(1) p53 deficient cell;

(2) tumor cell; or

(3) p53 deficient tumor cell.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each cell is structurally, physiologically, and functionally distinct.

H. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of expression detection are as follows (claims 45, 52, 58, 65, 73, 81):

(1) hybridization to a complementary nucleic acid;

(2) using an immunological reagent; or

(3) assaying for an activity of the cellular gene product.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each assay step requires distinct methods steps, reagents, response variables and criteria for success.

I. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of methods are as follows:

(1) further comprising the step of: assaying expression of one or more genes in Table 2B; and identifying compounds wherein expression of the genes in Table 2B is not greater in the presence of the compound than in the absences of the compound (claim 51 or 72);

(2) further comprising assaying the mammalian cell for cell growth and morphological features of senescence; and identifying compounds that induce senescence when expression of at least one cellular gene in Table 1 is lower in the presence of the compound than in the absence of the compound and the cells

are growth-inhibited and express morphological features of senescence in the presence of the compound (claim 55 or 76);

(3) further comprising assaying the mammalian cell for cell growth and morphological features of senescence; and identifying compounds that induce senescence when expression of at least one cellular gene in Table 1 is lower in the presence of the compound than in the absence of the compound and the cells are growth-inhibited and express morphological features of senescence in the presence of the compound (claim 55 or 76) and a method of claim 55 or 62 or 76 further comprising the steps of: assaying expression of one or more genes in Table 2B; and identifying compounds wherein expression of the genes in Table 2B is not greater in the presence of the compound than in the absence of the compound (claim 63 or 64 or 80); or

(4) not further comprising assaying additional genes in Table 2B or assaying for cell growth and morphological features of senescence.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each method is distinct requiring different method steps, objectives, response variables, and/or criteria for success.

If Applicant elects species "(1)" or "(3)" in I above, Applicants must elect a species in J below:

J. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of cellular gene are as follows:

Pick one or a specific combination of gene(s) from Table 2B.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each gene is structurally and functionally distinct.

Species Election for Group III

K. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of expression detection are as follows (claim 92):

(1) hybridization to a complementary nucleic acid;

(2) using an immunological reagent; or

(3) assaying for an activity of the cellular gene product.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each assay step requires distinct methods steps, reagents, response variables and criteria for success.

Species Election for Group IV

L. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of cellular gene are as follows (claim 98 or 104):

Pick ONE or a specific combination of genes from claim 98 or 104.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each gene is structurally and functionally distinct.

M. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of expression detection are as follows (claim 99):

(1) hybridization to a complementary nucleic acid;

(2) using an immunological reagent; or

(3) assaying for an activity of the cellular gene product.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each assay step requires distinct methods steps, reagents, response variables and criteria for success.

N. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of mammalian cell are as follows (claim 102):

(1) p53 deficient cell;

(2) tumor cell; or

(3) p53 deficient tumor cell.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each cell is structurally, physiologically, and functionally distinct.

O. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of mammalian cell are as follows:

(1) recombinant mammalian cell comprising a recombinant expression construct (claim 104); or

(2) a non-recombinant mammalian cell.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each cell is

structurally and functionally distinct requiring different agents, mechanisms of action, method steps, and criteria for success to accomplish the assay.

Species Election for Group V

P. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of senescence marker are as follows (claim 109):

Pick ONE marker from claim 109.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each marker is structurally and functionally distinct.

Q. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of expression detection are as follows (claim 111):

(1) hybridization to a complementary nucleic acid;

(2) using an immunological reagent; or

(3) assaying for an activity of the cellular gene product.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each assay step requires distinct methods steps, reagents, response variables and criteria for success.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not

distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura B. Goddard, Ph.D. whose telephone number is (571) 272-8788. The examiner can normally be reached on 7:00am-3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura B Goddard, Ph.D.
Examiner
Art Unit 1642